

2-26-04

Express Mail No.: EV 376 296 697 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: CHEN et al.

Confirmation No.: 3424

Application No.: 10/669,606

Group Art Unit: 1614

Filed: September 23, 2003

Examiner: Unassigned

For: Piperidine Derivatives

Attorney Docket No.: 11134-028-999

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application. This paper is being filed pursuant to C.F.R. § 1.34.

§ 1.34.		
1.	Enclos	ures accompanying this Information Disclosure Statement are:
	1a.	A list of all patents, publications, applications, or other information submitted for consideration by the office.
	1b.	A legible copy of:
		Each U.S. patent application publication and U.S. and foreign patent;
		⊠ Each publication or that portion which caused it to be listed on the PTO-1449;
		For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
		all other information or portion which caused it to be listed on the PTO-1449.
	1c.	An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
	1d.	Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2.		This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b): Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
		Within three months of the date of entry of the national stage as set forth in \$1.491 in an international application:

		Before the mailing of the first Office action on the merits;
		Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3.		This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.
		(Check either Item 3a or 3b)
	3a.	The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
	3b.	☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is: ☐ enclosed
		to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.
		(Item 3b to be checked if any reference known for more than 3 months)
4.		This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.
		The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:
		 enclosed. to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.
	The C	ertification Statement in Item 5 below is applicable.
5.		Certification Statement (applicable if Item 3a or Item 4 is checked)
		(Check either Item 5a or 5b)
	5a.	In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
	5b.	Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
	5c.	Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
6.		This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).
		(Check appropriate Items 6a, 6b and/or 6c)
	6a.	☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently

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OIPE	4C)			
	2006 B)		filed herewith.	
FEB 2 b	DEMARKS	6b.	Copies of publications listed on Form PTO-1449 from prior application Serial No., filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).	
A		6c.	Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.	
	7.		This is a Supplemental Information Disclosure Statement. (Check Item 7a)	
		7a.	This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .	
٠	8.		In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:	
·•			(Check Item 8a, 8b, or 8c)	
		8a.	satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.	
		8b.	set forth in the application.	
		8c.	enclosed as an attachment hereto.	
i.	9.	\boxtimes	The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.	
F	10.		No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).	
			Respectfully submitted,	
	ъ.		ary 24 2004 42,983	
	Date:	Febru	<u></u>	_
	•		For: Anthony M. Insogna (Reg. No. 35,203) JONES DAY 222 East 41 st Street	
			New York, New York 10017-6702 (212) 326-3939	

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FERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY DOCKET NO.	APPLICATION NO
11134-028-999	10/669,606
APPLICANT	
Chen et al.	
Chen count	
EILING DATE	GROUP

September 23, 2003

To be Assigned

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	5,219,860	6/15/93	Chambers et al.			
	A02	5,324,733	6/28/94	Billington et al.			
	A03	5,457,207	10/10/95	Efange et al.			
	A04	5,554,752	9/10/96	Efange et al.			
	A05	5,780,437	7/14/98	Goulet et al.			
	A06	6,200,957	3/13/01	Goulet et al.			
	A07	6,262,066	7/17/01	Tulshian et al.			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSL	ATION.
 						YES	NO
 A08	WO9614318	5/17/96	PCT				
 .A09	WO9721704	6/19/97	PCT				
 A10	WO9846569	10/22/98	PCT				
 A11	WO9964002	12/16/99	PCT				
 A12	WO0054772	9/21/00	PCT				
 A13	WO0006545	2/10/00	PCT				
A14	WO0107606	2/1/01	PCT				
A15	WO0206245	1/24/02	PCT				
 A16	EP 414289	2/23/94	EP				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

A17	An, et al., "Identification and Characterization of a melanin-concentrating hormone receptor" Proc. Natl. Acad. Sci. (2001) 98:7576-7581
A18	Bachner, et al., "Identification of melanin concentrating hormone (MCH) as the natural ligand for the orphan somatostatin-like receptor 1 (SLC-1)" FEBS Lett. (1999) 457(3):522-524.
A19	Barnes, et al. "Pharmacological Comparison of the Sigma Recognition Site Labeled by ³ Hhaloperidol in Human and Rat Cerebellum", Naunyn-Schmiedeberg's Arch Pharmacol (1992), 345:197-202.
A20	Bednarek, et al, "Short Segment of Human Melanin-Concentrating Hormone That is Sufficient for Full Activation of Human Melanin-Concentrating Hormone Receptors 1 and 2", Biochemistry (2001) 40:9379-9386.
A21	Bergeron, et al., "Biphasic Effects of Sigma Ligands on the Neuronal Response to N-Methyl-D-Aspartate", Naunyn-Schmiedeberg's Arch Pharmacol (1995), 351:252-260
A22	Bergeron, et al., "Effects of Low and High Doses of Selective Sigma Ligands: Further Evidence Suggesting Existence of Different Subtypes of Sigma Receptors ³ , Psychopharmacology (1997), 129:215-224.
A23	Boutin, et al, "Melanin-Concentrating Hormone and its Receptors: State of the Art", Can J. Physiol Pharmacol. (2002) 80:388-395.
A24	Chambers, et al. "Melanin-concentrating hormone is the cognate ligand for the orphan G-protein-coupled receptor SLC-1", Nature (1999) 400: 261-265.
A25	Chambers, et al. "Spiropiperidines as High Affinity, Selective 6 Ligands", J. Med. Chem (1992) 35: 2033-2039.
A26	Church, et al. "Blockade by Sigma Site Ligands of High-Voltage-Activated CA ²⁺ Channels in Rat and Mouse Cultured Hippocampal Pyramidal Neurones", Britsih J. of Pharmacology (1995) 116: 2801-2810.

A27	Couture, et al. "Some of the Effects of the Selective Sigma Ligand (+) Pentazocine Are Mediated Via a Naloxone-
	Sensitive Receptor" Synapse (2001) 39:323-331
A28	Efange, et al. "Spirovesamicols: Conformationally Restricted Analogs of 2-(4-Phenylpiperidine) Cyclohexanol (Vesamicol, AH5183) as Potential Modulators of Presynaptic Cholinergic Function" J. Med. Chem. (1994) 37: 2574-2582.
A29	Efange, et al. "N-Hydroxyalkyl Derivatives of 3β-Phenyltropane and 1-Methylspirol {1H-Indoline 3,4'-Piperidine}: Vesamicol Analogues With Affinity for Monoamine Transporters", J. Med. Chem. (1997) 40: 3905-3914.
A30	Gonzalez, et al., "alpha-Melanocyte-stimulating hormone (alpha-MSH) and melanin-concentrating hormone (MCH) modify monoaminergic levels in the preoptic area of the rat" <i>Peptides</i> (1997) 18:387-392.
A31	Hashigaki, et al. "Synthesis and Structure-Activity Relationship of Spiro [Isochroman-Piperidine] Analogs for Inhibition of Histamine Release. IV", Chem Pharm. Bull. (1984) 32(9): 3561-3568.
A32	Hawes, et al., "The melanin-concentrating hormone receptor couples to multiple G proteins to activate diverse intracellular signaling pathways" Endocrinology. (2000) 141: 4524-4532
A33	Hervieu, et al. "Similarities in cellular expression and functions of melanin-concentrating hormone and atrial natriuretic factor in the rat digestive tract", Endocrinology (1996) 137: 561-571.
A34	Hill, et al., "Molecular cloning and functional characterization of MCH2, a novel human MCH receptor" J. Biol Chem (2001) 276(23)20125-20129.
A35	Jezova, et al., "Rat melanin-concentrating hormone stimulates adrenocorticotropin secretion: evidence for a site of action in brain regions protected by the blood-brain barrier" <i>Endocrinology</i> . (1992) 130:1024-1029.
A36	Mclarmon, et al. "The Actions of L-687,384, a \(\text{o}\) Receptor Ligand, on NMDA-Induced Currents in Cultured Rat Hippocampal Pyramidal Neurons" Neurosci Letter. (1994), 174(2): 181-184
A37	Miller, et al. "Alpha-MSH and MCH Are Functional Antagonists in a CNS Auditory Gating Paradigm", Peptides (1993) 14: 431-440.
A38	Mori, et al., "Cloning of a novel G protein-coupled receptor, SLT, a subtype of the melanin-concentrating hormone receptor" Biochem. Biophys. Res. Commun. (2001) 283:1013-1018.
A39	Parkes, et al., "Contrasting actions of melanin-concentrating hormone and neuropeptide-E-I on posterior pituitary function" Ann NY Acad Sci. (1993) 680:588-90.
A40	Qu, et al., "A role for melanin-concentrating hormone in the central regulation of feeding behaviour" Naturet. (1996) 380:243-247.
A41	Rodriguez, et al. "Cloning and molecular characterization of the novel human melanin-concentrating hormone receptor MCH2", Mol. Pharmacol. (2001) 60(4): 632-639.
A42	Rossi, et al., "Melanin-concentrating hormone acutely stimulates feeding, but chronic administration has no effect on body weight" Endocrinology (1997) 138:351-355.
A43	Sailer, et al., "Identification and characterization of a second melanin-concentrating hormone receptor, MCH-2R." Proc. Natl. Acad. Sci., (2001) 98: 7564-7569.
A44	Saito, et al. "Molecular characterization of the melanin-concentrating-hormone receptor", Nature (1999) 400: 265-269.
A45	Saito, et al., "Melanin-concentrating hormone receptor: an orphan receptor fits the key" Trends Endocrinol. Metab. (2000) 11(8): 299-303.
A46	Shimada, et al., "Mice Lacking melanin-concentrating hormone are Hypophagic and Lean", Nature (1998) 396: 670-674.
A47	Wang, et al. "Identification and pharmacological characterization of a novel human melanin-concentrating hormone receptor, mch-r2", J. Biol Chem. (2001) 276(37):34664-34670.

EXAMINER DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.